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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/655,567	09/04/2003	Futoshi Okada	Furuya Case 1407	6434
23474	7590	07/10/2006	EXAMINER	
FLYNN THIEL BOUTELL & TANIS, P.C. 2026 RAMBLING ROAD KALAMAZOO, MI 49008-1631			KOSSON, ROSANNE	
			ART UNIT	PAPER NUMBER
			1653	

DATE MAILED: 07/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.



## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on June 21, 2006 has been entered. Claim 19 has been amended, claim 18 has been canceled, and claims 26-33 have been added.

### ***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 16, 17, 19, 24 and 25, drawn to a method of inhibiting the malignant progression of a tumor, classified in class 424, subclass 94.4.
- II. Claims 26-29, drawn to a method of inhibiting the change of a tumor from benign or dormant to malignant, classified in class 424, subclass 94.4.
- III. Claims 30-33, drawn to a method of inhibiting the genetic alteration of a tumor, classified in class 424, subclass 94.4.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, each of the different inventions has a different function and a different effect. As discussed by Applicants on May 22, 2006 in their response to final Office action in the previous application, three different claim sets are now

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pending, the first directed to a method of inhibiting malignant progression, the second directed to inhibiting the conversion from benign/dormant to malignant and third directed to a method of inhibiting genetic alteration. Therefore, these inventions are patentably distinct.

In this same response, Applicants stated that upon the indication that a particular claim set is allowable, the other two claim sets will be canceled. Examiner cannot discuss allowability at this point, but Group I has been previously rejected over prior art.

With respect to Group III, as discussed in the Advisory Action, genetic alterations are changes in the nucleotide sequences of genes. No gene sequences are provided in the specification. Thus, there is no evidence in the specification that administering SOD combined with gliadin inhibits changes in nucleotide sequences. In their RCE, Applicants assert that all changes in cells result in an alteration in the nucleotide sequences of genes and that the present invention presents a method of preventing genetic alterations as the benign or dormant tumors do not change to a malignant tumor. Applicants also assert that they are not required to show the genetic make-up of the benign or dormant tumors before and after the administration of gliadin-coated SOD.

In reply, the Group III claims do not recite gliadin-coated SOD; they recite, more broadly, SOD combined with gliadin. SOD combined with gliadin reads on wheat, as wheat contains SOD and gliadin. As for changes in cells, very few changes in cells result in alteration of gene sequences. Every biochemical reaction in a metabolic pathway in a living cell is a change in the cell, but the genes are not altered. Even during transformation to the malignant state, cancer genes are induced or turned on, but they have not been altered on the sequence level. As for not being required to show the genetic make-up of tumor cells before and after the administration of SOD combined with gliadin, how else would Applicants know that their method has produced alterations on the level of nucleotide sequences?

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Regarding Group II, as previously discussed, this method requires new searches, consideration and examination.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

**Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).**

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

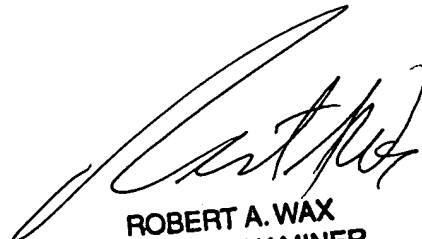

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached on 571-272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson  
Examiner, Art Unit 1653

rk/2006-06-29



ROBERT A. WAX  
PRIMARY EXAMINER